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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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June 6, 2008

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The Honorable Elias Zerhouni, M.D.
Director
National Institutes of Health
1 Center Drive, Room 126
Bethesda, MD 20892

Dear Dr. Zerhouni:

The National Institutes of Health (NIH) has played a vital role in improving the public health of the United States for more than a century. Given the enactment of the National Institutes of Health Reform Act of 2006, we expect that NIH research efforts will provide the foundation for future scientific and medical advancement.

We note with concern that the National Cancer Institute (NCI) has been recently caught in the middle of a dispute between clinical researchers over whether former smokers and others at high risk for lung cancer should be screened using computed tomography (CT) scans. The NCI is attempting to help resolve this dispute by investing \$200 million in a huge clinical trial called the National Lung Screening Trial (NLST), the largest cancer screening test ever conducted, hopefully generating data in 2010 to evaluate such CT scans. Last fall the leader of an advocacy group that favors such CT imaging for lung-cancer screening, unhappy that the NIH has not yet endorsed CT imaging, accused two researchers involved with NLST of bias and conflicts of interest because these researchers agreed to testify for tobacco companies about how screening might do more harm than good. The Majority side of this Committee has decided to pursue these accusations.

Several months later, the Cancer Letter and the New York Times published articles exposing potential conflicts of interest on the other side of the debate. These articles reported that the two leading researchers (part of a project known as the International Early Lung Cancer Action Project (I-ELCAP)) who claim unprecedented success with CT screening for lung cancer have a financial stake in CT scanning technology used in their studies. Although these I-ELCAP researchers applied for 27 patents and have accepted royalty income from one license, they did not properly disclose these financial interests in medical journal articles, according to the Cancer Letter and the New York Times. In addition, these publications reported that most of the funds supporting the I-ELCAP researcher project came from a tobacco company gift of \$3.6 million made to a foundation headed by one of the researchers.

It is not our purpose to weigh in on one side or the other in this dispute. Rather, our interest is in protecting America's interest in getting the best scientific evaluation on early lung cancer screening. To that end, we believe that there is a public interest in safeguarding the American taxpayer's \$200 million investment in the NCI's National Lung Screening Trial, and in ensuring the integrity of NIH research. In light of those concerns, we respectfully request that the NIH provide the following information by June 16, 2008:

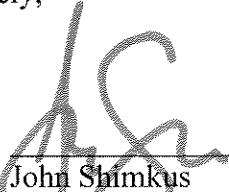
1. A status report on the NCI National Lung Screening Trial. Please include an explanation of NCI's expectation about the kind of data generated in 2010, and what kind of key results the NCI would be examining to reach any conclusions about the value of early lung cancer screening. Please identify any factors that could cause a delay in data being generated in 2010. Please also explain how the NCI has handled conflict-of-interest issues with respect to the researchers involved in the NLST.
2. Has the NCI audited the I-ELCAP data? If not, would the NCI be able to audit the data or be interested in auditing the data?
3. With respect to the I-ELCAP researchers, please explain whether the researchers individually or through their institution were receiving partial NIH support, and if so, whether they were required to disclose their financial stake in the CT scanning technology (including information on patents and royalties). If they were not receiving any NIH funds or they were not required to disclose, please explain under what circumstances a researcher receiving NIH funds would be required to disclose patent and/or royalty information. In addition, please explain whether and how NIH policy and/or regulations cover NIH-funded researchers who set up private foundations to receive donations that also support NIH-funded research projects. Finally, do NIH policy and/or regulations require disclosure to the human subjects of the researcher's financial interests in patents and/or royalties, or about private donations supporting the study? If so, please explain and detail what the nature of the disclosure involved. If not, why not?

Thank you for your consideration of this request. If you have any questions, please do not hesitate to contact Alan Slobodin and Karen Christian of the Minority Committee Staff at (202) 225-3641.

Sincerely,



Joe Barton
Ranking Member



John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Chairman
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations